

# Uganda

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## Logistics and Procurement Decisions and Issues for Consideration for Initiating and Expanding Access to ARV Drugs

The Logistics Subcommittee of  
the ARV Task Force  
Ministry of Health, Uganda

May 2003



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# Contents

Acronyms.....	v
Acknowledgements.....	vii
Executive Summary .....	ix
ARV Treatment Costs.....	ix
Key Decisions .....	x
Issues to be Addressed .....	xi
Recommendations .....	xi
1. Introduction.....	1
2. Current Situation .....	3
2.1 Background .....	3
2.2 Current Practices in Provision, Procurement, and Supply Chain Management of ARVs .....	3
2.3 Current Practices in Provision, Procurement, and Supply Chain Management of Laboratory Items.....	5
3. Overview of Key Logistics System Considerations for National ART Programs.....	7
3.1 Requirements of an Effective Logistics System.....	7
3.2 Logistics Management Issues in Scaling-Up ART Delivery in Uganda .....	8
4. Decisions Recommended by the Logistics Subcommittee .....	11
4.1 Policy and Legal Issues .....	11
4.2 Product Selection and the Essential Drugs List of Uganda.....	12
4.3 Drug Registration.....	12
4.4 Quality Assurance.....	13
4.5 Inventory Management: Storage and Distribution .....	14
4.6 Logistics Management Information System.....	15
4.7 Laboratory Requirements .....	16
5. Quantification of ARV Drugs for Public Sector Health Facilities Using World Bank MAP Funding .....	17
5.1 Background .....	17
5.2 Objective.....	17
5.3 Approach .....	17
5.4 Assumptions.....	18
5.5 Results.....	23
6. Policy Issues Defined by Logistics Subcommittee That Require Further Consideration .....	25
6.1 Statutory Basis for Importation of Generic Drugs into Uganda.....	25
6.2 Free Versus Subsidized ARVs in the Public Sector .....	25
6.3 Eligibility Criteria for Enrolling Patients .....	26
6.4 Revision of NDA Statute.....	27
6.5 Financing Logistics Management Costs: Procurement, Storage, Distribution, and LMIS .....	27
6.6 Standardizing Procurement Procedures and Coordinating Donated Products .....	28
6.7 Implementation of Uniform and Comprehensive Approaches to Data Collection and Management .....	30

## Uganda: Logistics and Procurement Decisions and Issues for Consideration for Initiating and Expanding Access to ARV Drugs

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6.8	Procurement and Supply Chain Management of Laboratory Equipment and Reagents.....	30
6.9	Integrating Donated ARVs into the Supply Chain Management System for ARVs Purchased by the Public Sector .....	31
7.	Recommendations for Implementation .....	33
7.1	Program Issues .....	33
	<i>Action Items</i> .....	33
	<i>Action Items</i> .....	33
7.2	Product Selection and Registration .....	34
	<i>Action Items</i> .....	34
	<i>Action Items</i> .....	34
7.3	Quantification, Forecasting, and Procurement .....	34
	<i>Action Items</i> .....	34
	<i>Action Items</i> .....	35
	<i>Action Items</i> .....	36
7.4	Logistics Management Information System .....	36
	<i>Action Items</i> .....	36
7.5	Inventory Management, Storage, and Distribution .....	37
	<i>Action Items</i> .....	37

## Annexes

Annex 1: Scope of Work .....	39
Antiretroviral Task Force—Technical Assistance Consultancy .....	41
Background .....	41
General Scope of Work .....	42
Specific Scope of Work .....	42
Annex 2: Schedule of Activities .....	43
Schedule of Activities .....	45
Annex 3: List of Accredited Centers and Pharmacies Authorized to Distribute Antiretrovirals.....	47
List of Accredited Centers and Pharmacies Authorized to Distribute Antiretrovirals .....	49
List of Authorized Pharmacies as of February 2003 .....	49
Annex 4: Results of ARV Quantification.....	51
Report from Site Visit to Masaka Regional Hospital ARV Treatment Center .....	53

## Tables

Table 1: Recommended Tests for Patients Accessing ART through the Public Sector .....	16
Table 2: Standard Treatment Regimes for ARV Drugs Recommended by the Clinical Care Subcommittee of the ARV Task Force, 1 March 2003.....	18
Table 3: Estimates for Number of Adults and Pediatric AIDS Cases That Will Receive ART through the Public Sector .....	21

# Acronyms

ACP	AIDS control program
AIDS	acquired immune deficiency syndrome
CDC	Center for Disease Control and Prevention
CPHLS	Central Public Health Laboratory Services
EDLU	Essential Drugs List for Uganda
EFV	efavirenz
GFATM	Global Fund for AIDS, Tuberculosis and Malaria
GOU	Government of Uganda
GSK	Glaxo Smithkline
HIV	human immunodeficiency virus
HIV/AIDS	see HIV and AIDS
JCRC	Joint Clinical Research Centres
JMS	joint medical stores
JSI	John Snow, Inc.
LMIS	logistics management information system
MAP	Multi Country AIDS Program
MOH	Ministry of Health
MOS	months of supply
NDA	National Drug Authority
NGO	nongovernmental organization
NMS	National Medical Stores
OI	opportunistic infection
PEP	post-exposure prophylaxis
STI	sexually transmitted infections
TB	tuberculosis
UAC	Uganda AIDS Commission
USAID	United States Agency for International Development
UVRI	Uganda Virus Research Institute
VCT	voluntary counseling and testing (HIV)
WB	World Bank
WHO	World Health Organization (Geneva, Switzerland)





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This report is dedicated to PLWHA in Uganda, and the many individuals from communities, NGOs and other organizations, and the MOH who have consistently fought for access to ART in Uganda.

The views stated in this report are those of the authors, and do not necessarily reflect the views of the U.S. Agency for International Development or the Uganda Ministry of Health.



# Executive Summary

Of the 2 million people living with AIDS (PLWHA) in the country, the Government of Uganda (GOH) estimates that at any one time, about 100,000 need of antiretroviral therapy (ART). ART has been available in Uganda since 1998, but it was provided mainly through the private sector, some employers, and a small number of research or pilot projects. With the recent availability of low-cost, high-quality generics, often in fixed-dose combinations, the government is now able to explore the feasibility of public sector access to ART.

To guide and facilitate the expansion process, the AIDS Control Program of the Ministry of Health (MOH) has set up a cross-disciplinary, multi-sectoral ARV Task Force, with five subcommittees. The subcommittees produce policies and guidelines for clinical care, finance, logistics, and procurement and advocacy, all of which will feed into the National ARV Policy. The primary purpose for the national guidelines was to provide a consistent framework for implementers to use while expanding ART availability in the public sector. The policy and guidelines will also enable MOH to access U.S.\$3 million dollars in funding for procurement of ARV drugs through the World Bank Multi Country AIDS Program (MAP), and to assist the MOH/Government of Uganda in preparing their proposal to the Global fund for AIDS, Tuberculosis and Malaria (GFATM) in May 2003, in round three.

The consultancy was to assist the logistics and procurement subcommittee of the ARV Task Force to—

- Finalize quantification of U.S.\$3 million for ARVs, to be procured with World Bank MAP funding.
- Document existing logistics and policy decisions.
- Identify outstanding issues requiring further decision making.
- Assist in planning for the additional activities that the logistics subcommittee must complete.

During the process of finalizing the quantification, members of the logistics subcommittee worked with those from the clinical care committee to select the final standard treatment regimens, which were based on clinical criteria and considered the financial and logistics implications of clinical decisions.

## ARV Treatment Costs

*The results of the quantification demonstrated that, based on the lowest cost estimates for drugs, it will cost approximately \$520,000 to treat 1,000 ARV cases per year or \$520 per patient, per year. This figure is higher than the cost of the lowest combination regimen on the market because estimates were made for 1,000 cases, and it captured the costs associated*

with switching from first-line to alternate lines of therapy and for treating pediatric AIDS cases. It also includes the cost of a four-month supply of drugs that will be a buffer stock at the central level. Without the additional cost of ARV drugs for the buffer stock, estimated costs of treatment are \$390 per patient, per year.

In addition, the figure of \$520 only includes the cost of ARV drugs and does not include costs for laboratory tests or treating and preventing opportunistic infections. Laboratory costs are estimated to range from \$43–\$220 per patient per year, depending on the type and number of lab tests conducted. An average annual cost per patient of \$80 for laboratory tests was estimated in Uganda's GFATM round three proposal.

## **Key Decisions**

The logistics subcommittee has made the following ten key decisions:

1. Adopting a standardized and coordinated procurement approach, including limiting the number of agents.
2. Procuring ARV drugs through limited competitive bidding mechanisms, using prequalified suppliers.
3. Developing specifications for low-cost, high-quality drugs, including generics.
4. Implementing fast track registration of ARV drugs by the National Drug Authority (NDA).
5. NDA instituting a system of routine analysis of each batch of imported drugs rather than mandatory analysis.
6. Adding all ARV drugs included in the standard treatment regimen to the Essential Drugs List of Uganda.
7. Distributing public sector ARV drugs through NMS.
8. Creating a logistics management information system (LMIS) for ARV drugs prior to their arrival.
9. Limiting patient access to ARV drugs only to accredited treatment and dispensing centers.
10. Centralizing control and inventory management of alternate and second-line ARV drug regimens.
11. Strengthening the logistics management system for laboratory reagents and supplies.

## Issues to be Addressed

The logistics subcommittee identified a number of issues that require further decision making and consideration. They recommended development of policies to—

1. Ensure that any legislation related to drug patents and importation of generic drugs takes advantage of recent Doha concessions and is consistent with WTO and TRIPS agreements.
2. Determine the extent of subsidies for patients purchasing ARV drugs in the public sector, and determine when and if drugs will be provided free.
3. Develop eligibility criteria for enrolling patients, considering that there will not be enough ARV drugs available through the public sector to treat all who need them.
4. Ensure sufficient and sustained financing for procurement, storage, distribution, and maintaining an LMIS for ARV drugs.
5. Confirm the institution responsible for overseeing management of laboratory equipment, reagents, and supplies to support ART expansion.

## Recommendations

In addition to policies, the logistics subcommittee members and other relevant partners require further action for implementation in a number of areas. Following are urgent recommendations from the consultancy.

The logistics subcommittee should develop—

- three 5-year ARV drug forecasts and flexible procurement mechanism
- long-term financing mechanism for purchasing ARV drugs to minimize the risk of prolonged stockouts, both at the national and treatment levels
- LMIS and inventory control procedures *prior* to the arrival of ARV drugs in Uganda
- procedures for secure storage and distribution that preserve ARV drug quality
- mechanism to provide feedback on drug consumption rates, and patterns to ensure that changes in prescribing and dispensing patterns are rapidly incorporated into national forecasts and procurement plans.



# 1. Introduction

The logistics and procurement subcommittee of the ARV Task Force requested this report be prepared to—

- Finalize quantification of \$3 million in ARVs to be procured with World Bank Multi Country AIDS Program (MAP) funding.
- Document relevant logistics information and key policy decisions available to date.
- Identify outstanding critical issues and gaps in implementation that have yet to be addressed.
- Assist in planning for the additional activities that the logistics subcommittee must complete.

USAID funded the consultancy through the JSI/DELIVER Uganda project. The consultant was in Uganda, in 2003, from February 23–March 4, March 17–28 and May 18–28 (see annex I for the scope of work).

The approach taken during the consultancy included information gathering, advocacy for decision making through individual and group interviews/discussions, official meetings, and reviewing background documentation. A site visit was made to Masaka Regional Hospital's ARV clinic to record practical, field-based observations and challenges. The consultant prepared a draft report for discussion, which was presented to logistics subcommittee members on March 14, 2003 for comments. See annex 2 for a detailed schedule of activities.

The report is divided into sections.

Chapter 2 presents the current situation and includes a summary of ART service provision and a brief description of procurement and logistics system operations for drugs and laboratory supplies.

Chapter 3 is an overview of key logistics considerations for an expanded ART program.

Chapter 4 documents decisions that logistics and other subcommittees have made that are pertinent to logistics system implementation.

Chapter 5 presents the decisions that have already been made, translated as one-year quantification for ARV drugs using World Bank MAP funding.

Chapter 6 presents issues and questions for the MOH that must be addressed before the National Policy and Guideline documents are finalized. Chapter 6, the final chapter, lists recommendations and next steps for implementation of a logistics system for ARVs.





## **2. Current Situation**

### **2.1 Background**

The Government of Uganda estimates that of approximately 2 million PLWHA, 100,000 need antiretroviral therapy (ART). Although ART has been available in Uganda since 1998, to date, it has not been provided widely through the public sector, primarily because of lack of funding for these high-cost drugs. A secondary factor, which has also been cited, is the fear of poor compliance due to the high pill burden, strict dosing intervals, and numerous side effects. Currently, ART is primarily provided through the private sector, some employers, and a small number of research or pilot projects. With the recent availability of low-cost, high-quality generics, often in fixed-dose combinations, the government can now explore the feasibility of public sector access to ART.

Uganda is in the process of developing a national policy and guidelines for introducing and expanding access to ART in the public and private sectors. The Ministry of Health, through the AIDS Control Programme (ACP), is leading the process, under the mantle of the ARV Task Force and its subcommittees. The five subcommittees are Policy, Advocacy, Clinical Care, Logistics and Procurement, and Financing. Representation on these subcommittees is cross disciplinary and includes members from private, civil society, and public sector partners implementing ART in the country. The ARV Task Force, chaired by Dr. Peter Mugenyi of the Joint Clinical Research Centres (JCRC) and its subcommittees, was established in November 2002.

Currently, all the subcommittees are in the final stages of developing their respective sections of the national policy and guidelines. The primary purpose for the documents is to provide a consistent framework for implementers to use while expanding ART availability in the public sector. Furthermore, the development of policy and guidelines will also enable the MOH to access U.S.\$3 million dollars of funding for procurement of ARV drugs through the World Bank MAP Project, and to assist the MOH/Government of Uganda (GOU) in preparing their proposal to the Global fund for GFATM in round three, expected in April 2003. For this submission, both proposed policies and procedures for ART treatment must be included, as well as quantification for commodities to be requested under the GFATM project. The GFATM proposal includes about \$6 million in funding for ARVs over three years.

### **2.2 Current Practices in Provision, Procurement, and Supply Chain Management of ARVs**

Currently, ARVs are procured mainly through the private sector by Medical Access Uganda Limited, a not-for-profit company that was started under the Drug Access Initiative, and the

Joint Clinical Research Centre.<sup>1</sup> Three wholesaler pharmacies—Star Pharmaceuticals, Shurik, and Surgipharm—also import ARVs, as does one retail pharmacy, Rene Pharmacy.<sup>2</sup> Health facilities are currently providing ART purchase drugs from various importers described earlier, and they stock small quantities that can be purchased by patients.

Costs for the drugs vary significantly depending on whether they are branded or generic. Although branded drugs are usually more expensive, this is not always the case. Currently, there are 46 registered ARVs, including 16 from 4 manufacturers in India, 2 from South Africa, and 28 from Europe and the United States. Sixteen ARVs are pending registration.

Twenty-two sites in Uganda are accredited to provide ART, of which 18 are operating. This includes seven of the 11 regional hospitals: Arua, Mbarara, Mbale, Kabale, Lira, Masaka, and Gulu, as well as Mulago National Referral Hospital. Most of the private and NGO sites that provide ART are in or around Kampala. It is estimated that about 10,000 people in Uganda are currently on ART, and approximately 1,000 access these services through public sector facilities. See annex 3 for a full list of accredited centers and pharmacies.

JCRC is the largest ART service provider in the country, giving approximately 50 percent of the care to adult patients on ARVs. In 2002, 1,070 patients accessed ART from JCRC, of which 48 percent were female and 52 percent were male.<sup>3</sup> Mildmay International Center, which has a specialized center for pediatric HIV/AIDS care and support, has the highest number of children on ART—105 or just under 50 percent of children known to be receiving ART in Uganda.

No existing supply chain that stores and distributes ARVs below the central level can be used to manage drugs for an expanded ART programme. Medical Access is currently a major supplier, but it operates on a cash-and-carry system, and sells only branded drugs. Obvious choices for consolidating procurement and logistics are the National Medical Stores (NMS) and Joint Medical Stores (JMS), currently the largest providers of all other essential drugs to the public and NGO sectors. Both NMS and JMS are licensed to import ARVs, although neither are doing so. These organizations could potentially conduct procurement, storage, and distribution of ARVs for an expanded program, although details on procedures and financing must be agreed upon.

Data management for ART has been identified as an area that needs significant improvement.<sup>4</sup> The majority of ART centers use manual methods for data management, including for patient monitoring. A few sites with computerized systems use either a database developed by the Centers for Disease Control and Prevention (CDC) or their own systems. Nonetheless, data retrieval and analysis for the rapid assessment was difficult, and most

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1 ARV Task Force, MOH Uganda. March 2003. *Implementation Guidelines for ART in Uganda*. Kampala, Uganda: MOH Uganda.

2 National Drug Authority. February 21, 2003. *List of Accredited Centres and Pharmacies authorized to distribute antiretrovirals*.

3 Akol, Z., E. Namagala, E. Aceng, and J. Serutoke. November 2002. *Draft Report on Rapid Assessment of Access to ART in Uganda*. Uganda: Ministry of Health and World Health Organization.

centers identified this as a challenge. Logistics data for ARVs is not routinely collected or reported, therefore, it is likely a new LMIS will have to be developed.

## **2.3 Current Practices in Provision, Procurement, and Supply Chain Management of Laboratory Items**

Central Public Health Laboratory Services (CPHLS), based in Kampala, has the mandate for procurement, logistics management, and oversight for quality assurance and management of laboratory equipment and supplies for all regional, district, HC IV, and HC III labs in the country. Initial screening for HIV in Uganda at the beginning of the epidemic (1987–1990) was done at CPHLS, which also had oversight for HIV-related lab supplies and equipment. In the early 1990s, Uganda Virus Research Institute (UVRI), based in Entebbe, took over the mandate for HIV tests and supplies while CPHLS was undergoing renovation. Although, initially, this was only a temporary arrangement, partly because of funding constraints, CPHLS no longer procures and supplies any HIV-related lab equipment and supplies. UVRI currently gives the MOH procurement committee advice on HIV equipment and supplies to purchase, while CPHLS does so for all other lab equipment and supplies. CPHLS has significant funding constraints, and it receives most of its funding from the World Health Organization (WHO), with smaller amounts from MOH/Uganda and CDC. Quantification of non-HIV related laboratory requirements is based on budget rather than actual needs, and CPHLS is able to purchase about 80 percent of requirements locally, through JMS. UVRI quantifies HIV-related equipment and supply needs, and provides these figures to the MOH for procurement.

Medical supplies (including laboratory supplies) imported into Uganda are usually subject to a importation duty of 0.8 percent of the pro-forma value. However, any drugs or medical supplies directly connected to HIV/AIDS prevention, care, or treatment are exempted from importation duties. When lab supplies or reagents are imported, the National Drug Authority (NDA) notifies UVRI, which performs quality control tests before authorizing NDA to import them into the country.

There is no systematic way to distribute lab supplies in the public sector. Delivery from the central level to lower levels is either by CPHLS or UVRI vehicles, depending on the type of lab item. However, this is not necessarily done on a regular basis or according to needs. When CPHLS is able to purchase supplies, distribution is done on an allocation system based on the essential tests required at each level. Mainly due to funding constraints, most labs at district and HC IV and III levels experience chronic shortages of required reagents. Although districts are supposed to include the purchase of lab supplies in their budgets, most districts, at present, are not doing so.



### **3. Overview of Key Logistics System Considerations for National ART Programs**

#### **3.1 Requirements of an Effective Logistics System**

The capacity to reliably, consistently, and securely supply the commodities needed to support ART service delivery is indispensable to the success of HIV/AIDS programs. In both the public and private sectors, program planners are increasingly aware of the importance of effective supply chains, because logistics improvements bring important, quantifiable benefits. Strong supply chains benefit programs in four important ways:

- increased program impact through consistent, reliable supply of essential products
- enhanced quality of care through the delivery of high-quality products
- improved accountability through reduction of loss and wastage
- increased support of critical stakeholders by ensuring the integrity of the supply chain.

These benefits are of particular importance in ART implementation at a national level in resource constrained settings. Most of the caution expressed by governments and donors in widely introducing ARVs in these settings has been the fear of potential negative outcomes associated with delivering expensive, highly potent medications. Following are a few examples of outcomes that can be prevented or minimized by implementing an effective logistics system:

- Emergence of widespread drug resistance associated with an interrupted supply or poor quality drugs.
- Leakage from the public sector into the unlicensed private sector or to other countries, thus disrupting global pricing patterns and increasing the likelihood of resistance.
- Increased expense to programs, which have insufficient funds to buy drugs for essential health problems. Logistics cannot expand the total resource envelope, but it can ensure that available resources are used efficiently and wastage is minimized.

## 3.2 Logistics Management Issues in Scaling-Up ART Delivery in Uganda

It is important to remember that while much of the focus in the following section is on the immediate logistics considerations for implementing a national ART program, ultimately the decision-making process must consider the larger geo-political context.

Uganda, Kenya, and Tanzania are moving toward the creation of an East African community with *no borders*. In practice, there is already significant cross-border movement, with minimal restrictions, and sharing of health services next to border areas. Therefore, especially in an environment where generic importation or local manufacturing of ARVs is enabled in one or two countries, but not in all, *harmonized legislation, registration and quality control standards and pricing policies are considerations for long-term goals for ART programs in each of these countries.*

3.2.1 *An integrated approach is required to examine the logistics implications of HIV/AIDS. Although ARVs are the single most expensive commodity, HIV/AIDS prevention, diagnosis, counseling, and treatment programs require more than 120 distinct products to operate effectively.*

3.2.2 *The role of the public and private sector in drug procurement and logistics needs to be carefully defined.* If the public sector wants to take the lead, it will have to carefully consider incentives that encourage the private sector to participate as partners in the program. Public-private partnerships, including NGOs and civil society organizations, are essential.

3.2.3 *A supportive policy and legal environment must exist for all the logistics functions to operate effectively and efficiently.* The National Drug Authority is willing for generic drugs to be registered and imported into the country; two local Ugandan pharmaceutical manufacturing companies have applied for permission to begin local production of ARVs. As long as there are no legal barriers for importation and local production, this will probably further reduce the price for ARVs to less than they currently cost. *Policies are also required for determining how candidates for ART are selected, provider qualifications, treatment sites, and referral systems; and ARV prescribing and dispensing guidelines.*

3.2.4 *ARV product selection for first- and second-line regimes and specific subgroups, such as tuberculosis patients and post-exposure prophylaxis (PEP) for health workers, should provide clear guidance for program managers and implementers.* In addition, because fixed-dose combinations often offer a significant benefit to improving adherence, the guidelines should address preferences for specification of the regime in terms of pill burden. *ARVs should be included on the Essential Drugs List and user-friendly standard treatment guidelines developed for service providers.*

3.2.5 *Supplier selection consistent with the selected products will be complimentary to the ARV product selection.* Supplier selection should be done based on the country's past experience with manufacturers, as well as reference to WHO's list of pre-qualified suppliers

whose products have been evaluated and recommended by WHO as high-quality, efficacious drugs, appropriate for resource limited settings.<sup>4</sup>

*3.2.6 A balance needs to be made between thoroughness and speed in the registration of all new products for initial and ongoing quality control.* This applies both to imported and local manufacturers. Delays in registration should not become a way to protect local monopolies.

*3.2.7 Financing and ability to pay will greatly impact the demand for ARVs and, thus, the distribution of the products.* While the importation of generics into Uganda has and will continue to significantly reduce the cost for first-line therapy down to U.S.\$1 a day—or \$350 per patient per year—this is the equivalent of the average annual per capita income of Ugandans (U.S.\$360). The official government policy is that there is no cost-sharing for medications in the public sector, but discussion is still ongoing as to when to provide ARVs free or at a subsidized cost. If, for example, there is a 50 percent subsidy, even the cheapest (first-line) regimen is likely to be unaffordable for the majority of Ugandans. Another issue are the cost of the required diagnostic agents for laboratory testing to monitor and manage treatment, which still remain high and are, potentially, a major constraint to expanding implementation of ART.

*3.2.8 Drug quantification.* Because, currently, there are insufficient funds to procure ARVs to treat everyone who needs them, quantification initially can only be done based on available funding and for a defined target population. *A crucial input for ARV quantification is the need for clear guidelines for service providers about criteria for providing first- and second-line, and alternate treatment regimens for those eligible to receive ART.* Following an assumption-based quantification methodology, data on actual consumption and stock levels at the service delivery site to accurately estimate commodity requirements must be collected and reported, generally through a LMIS.

*3.2.9 Procurement.* The need for quality management throughout the supply chain of ARV drugs makes procurement using international competitive bidding a greater than ordinary risk. This gains importance because there are likely to be multiple procurement agents buying the drugs, depending on the funding source, for example, MAP, GFATM, etc. *The ideal solution would be to use a single procurement agent. If, this is impossible, the procurement procedures, including options such as pre-qualified tendering and use of identical specifications, can be standardized.* Furthermore to reduce duplication and enhance supply chain management of ARVs, quantities to order and procurement cycles among various donors and procurement agents must be coordinated.

*3.2.10 Inventory management, storage, and distribution.* The value of ARVs, cost as well as life-saving potential, creates an incentive for mismanagement and pilferage if appropriate inventory control procedures and systems are not designed. Therefore, *strict monitoring of inventory levels and secure transportation and storage facilities will be needed.* A decision

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4 World Health Organization (WHO). February 2003. *Pilot Procurement, Quality and Sourcing Project: Access to HIV/AIDS Drugs and Diagnostics of Acceptable Quality*. (Suppliers whose HIV-related products have been found acceptable, in principle, for procurement by UN agencies).

has been made to distribute and store the ARVs through the existing system, using NMS. New procedures for handling ARVs should be as consistent as possible with existing procedures for handling high-cost or classified drug items at hospitals or facilities.

3.2.11 For the logistics system to operate effectively and to ensure the availability of quality products at service delivery points, a well-functioning LMIS is required. *Close monitoring of ARV drug consumption and stock levels is particularly important to ensure an adequate supply of quality drugs, respond to changes in demand, manage increased volumes of commodities, and minimize pilferage and misuse.* The LMIS should be designed and in place before ARV distribution begins.



## 4. Decisions Recommended by the Logistics Subcommittee

### 4.1 Policy and Legal Issues

*In the interests of enhancing access, the subcommittee encourages procurement of lowest cost ARV drugs—including generics—as long as drug quality is assured*

NDA has taken a neutral position on importation of generic ARVs. If the quality of imported drugs is assured, NDA will not concern itself with patent issues.<sup>5</sup> Furthermore, three local companies—KPI, UPL, and Rene Pharmacy—have applied to begin manufacturing ARVs in Uganda. NDA has issued a position paper on local production to provide guidelines to these companies. While the companies are gearing up for local manufacture, they will import finished drugs in bulk from their sister companies in India, then repackage them locally. This stance on purchasing either generic or branded ARVs is supported by the MOH policy on ART—to support GOU’s strategy on enhancing equitable access to ARVs by all Ugandans, low-cost, high-quality drugs will be purchased, regardless of patent status. Uganda is also developing a law that will allow importation and use of generic ARVs, according to WTO TRIPS agreements.

Innovator companies have registered patents for seven ARV drugs in Uganda,<sup>6</sup> of which five are included in the recommended standard treatment regimens. GlaxoSmithKline has registered patents for Combivir®, Lamivudine®, and Zidovudine®; Boehringer Ingelheim for Nevirapine®; and Agouron for Nelfinavir®. GlaxoSmithKline also has patents registered for Abacavir® and Amprenavir® (neither of which are currently included in the standard treatment guidelines).

*The subcommittee recommends that all ARVs, particularly those bought through the public sector, should be channeled through either accredited pharmacies or dispensing centers, both within health facilities, or at retail outlets*

In 2003, treatment will begin at 12 regional hospitals using the new supply of ARVs; some hospitals are already providing ART. In 2004, services will rollout to 50 percent of the district hospitals, and expand to the remaining district hospitals in 2005. The MOH policy is that only accredited treatment centers will receive drugs procured and distributed through the public sector. Ideally, ARVs should only be available at accredited centers or through accredited physicians, but it is recognized that this will be difficult to regulate in the private sector. NDA, however, does have the mandate to only accredit a limited number of private sector pharmacies to stock and dispense ARVs; therefore, it is possible to control the drug supply in the private sector.

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5 National Drug Authority. September 2002. “Draft Position Paper on Antiretroviral Drugs.”

6 Attaran, Amir, and Lee Gillespie-White. “Do Patents for Antiretroviral Drugs Constrain Access to AIDS in Africa?” *JAMA* 286 (October 17, 2001) 1886–1892.

The existing accreditation criteria for treatment centers do not include comprehensive or sufficient measures to assess pharmacy, drug, and logistics management capacity. Subcommittee members, led by NDA, are reviewing and improving criteria that can be used to accredit pharmacies or dispensing centers. The committee considers it important to accredit dispensing sites within public sector treatment sites, as well as dispensing pharmacies in the private sector, both to ensure quality within the private sector and to broaden access in case of stockouts or shortages within the public sector sites. The development of revised accreditation criteria for pharmacy, drug, and logistics management will be in-depth and will include elements on training, storage, inventory control, record keeping, and reporting; and measures to reassess accredited sites to ensure standards are maintained over time.

## **4.2 Product Selection and the Essential Drugs List of Uganda**

*All ARVs recommended for use by the clinical care committee will be considered essential drugs, and will be added to the Essential Drugs List of Uganda (EDLU) during the next revision.*

The Clinical Care subcommittee of the ARV task force has finalized standard treatment regimes for first- and second-line therapy, treating tuberculosis (TB)/HIV patients and PEP for occupational exposure in health workers. The logistics subcommittee has also determined that ARV drugs in the standard regimes are considered essential drugs and will be included on the EDLU, either in the next revision or as an addendum to be published immediately.

## **4.3 Drug Registration**

*To minimize delays related to drug registration, NDA has published a position paper on procedures for registering ARVs, including generics.*

NDA has well established, clearly defined processes for companies to apply to register any new drugs, formulations, and strengths for the Ugandan market. However, in recognizing the importance of ensuring availability of high-quality, low-cost ARVs on the market, NDA has issued a position paper that clearly outlines procedures to be followed for registering ARV drugs, particularly generics.

Currently, NDA estimates that it takes a minimum of 3–6 months from the time of a drug application to the time of registration. Generally, due to delays in documentation and communication, the average duration for new drug registration is about one year. Every time a new drug application is received, NDA must inspect the factory producing that product for GMP (depending on the country of manufacture) for each different product category. For example, if a generic manufacturer in India has antibiotics registered for the Ugandan market, but has applied to register an ARV, NDA must reinspect that manufacturing site for the category of ARVs. If, however, the manufacturer already has one or more ARVs registered for the Ugandan market and it is applying for a third, inspection is not necessary.

NDA generally only conducts factory inspection visits twice a year. Following factory inspection, a full evaluation of the application dossier is conducted.

*To enhance access, NDA and the subcommittee have agreed to fast-track registration of ARVs.*

Because the registration process can be lengthy, ARVs are treated as a high priority and NDA has instituted a fast tracking registration process to be applied for new drug applications for ARVs. The average duration for registration in this case is 1–3 months. It is important to note that each new strength of a drug requires a separate application. For example, there are already several strengths of ddI tablets registered in Uganda (100 mg, 25 mg), Merck & Co. must submit a separate application to register the new strength of 200 mg tablets.

## 4.4 Quality Assurance

*To minimize delays in receiving and distributing ARVs, NDA will carry out routine analysis, rather than mandatory analysis, for this category of drugs.*

As part of its efforts to ensure the quality of all imported drugs, NDA requires each batch of incoming drugs to be accompanied by a certificate of analysis from the manufacturer (instead of the supplier). However, for certain categories of drugs (TB and anti-malarials), mandatory analysis is also conducted, which means that a sample of drugs is taken from the incoming shipment and tested for quality. The products are held under customs control while the testing takes place, which could be any time from 3–14 days.

All other drugs are subject to routine analysis, which essentially means certificates of analyses are assessed and the drugs are released to the program without any testing at the port, if all documents and physical attributes are compliant with NDA's statutory requirements. Quality assurance for these drugs is conducted through post-market surveillance sampling by drug inspectors. NDA will observe this situation, however, and if, in the future, quality for ARVs is not meeting expected standards, NDA will switch from routine to mandatory analysis for imported ARVs.

To increase NDA's capacity in post-market surveillance, WHO has trained drug inspectors to evaluate ARVs for quality. NDA will also expand its regional presence from three to seven regions, and they intend to set up a Drug Information Pharmaco-vigilance Center, funded by WHO, which is expected to be operational after July 2003. Information will be collected on adverse drug reactions, and quality tests will be conducted both at the time of importation and also during post-market surveillance. Relevant information will be shared with health professionals and entered into a data bank. The data bank will be developed so NDA can track the source of quality deterioration, either to the manufacturer or during storage and handling during distribution.

## **4.5 Inventory Management: Storage and Distribution**

*NMS will store and distribute ARVs procured for use in public-sector health facilities. A vertical system for storage and distribution will not be set up for this category of drugs.*

The logistics subcommittee has taken the long-term view for logistics management of ARVs. Thus, ARVs procured through the public sector (MAP, GFATM, etc.) will not bypass the existing storage and distribution systems. They will be stored at the NMS warehouse and distributed through an agreement with NMS. Again, this decision is reflected in the MOH Policy on ART,<sup>7</sup> which states that all ARVs destined for public health facilities will be purchased or ordered through NMS. To ensure that drug flow continues while NMS builds up its capacity in the area of ARVs, the policy has a clause that allows facilities to obtain ARVs elsewhere if ARVs from NMS do not meet quality standards or are not available.

It is thought that having a limited number of importers/suppliers of ARVs in the country will greatly facilitate the quality and low costs of these items. It is the MOH's view that NMS can be a significant supplier of low-cost, high-quality ARVs that are available for purchase by public, NGO, and private facilities in Uganda. By providing a reliable and consistent supply of low-cost, high-quality drugs, NMS can help squeeze out small, unlicensed ARV drug sellers, minimizing the risks of counterfeit or low-quality drug availability on the market and reducing the government's regulatory burden.

*To minimize the risk of expired stock, imported ARVs must be received with a minimum of two years or 75 percent of their shelf life remaining.*

The shelf life for the majority of ARVs falls between 18–36 months. Consistent with the policy for other drugs imported into Uganda, to reduce the risk of expiry, ARVs will have a minimum requirement of shelf life when they arrive in country. ARVs may not be dispensed as rapidly as expected, particularly during the initial expansion period when demand and uptake is uncertain and especially at new sites; therefore, it is prudent not to accept drugs with less than the required shelf life.

*ARVs for second-line treatment, and option B of first-line treatment, will be maintained at NMS and distributed to lower levels “as needed,” both to reduce inventory holding costs and to ensure the rational use of ARVs.*

The logistics subcommittee made another important decision to maximize the use of resources by reducing the amount of buffer stock required at ART treatment centers. This decision pertains mainly to the ARV supply for adult cases receiving option B of first-line treatment and second-line ARVs, which will not be required in large quantities or by all patients during the first year. Option B of first-line treatment is intended for those patients who develop toxicity for option A, or the fixed dose combination of D4T+3TC+NVP. Rather than assuming that every site will require these drugs, and estimating an average quantity per site that is likely to be inaccurate, ARVs for these two purposes will be centrally maintained

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7 Uganda Ministry of Health. March 2003. *Antiretroviral Treatment Policy for Uganda*. Kampala: Uganda Ministry of Health.

and sent out as needed. Courier services that serve the majority of the country can be used for rapid distribution of these drugs. Although these services are likely to be costly relative to NMS distribution, such contracts will ensure timely and consistent deliveries and are still likely to cost less than maintaining higher buffer stocks of the drugs at each site.

Although such an approach might result in a 3–5 day delay in patients being able to start treatment with these regimes, there are two significant benefits to this approach. First, the quantities required to maintain a buffer stock only at the central level are significantly lower than those required for buffer stocks at every site (in other words, the program has less money tied up in inventory levels of ARV drugs). Thus, both in terms of relative volume and absolute cost, funds are available to treat more patients. Maintaining a central stock of these items will also minimize the risks of loss through pilferage and expiry by facilitating the tracking of inventory levels.

Second, the ART program manager within the MOH will be able to better track information on drug substitution and regime switching, because they will be closely involved in authorizing distribution of these drugs. This information can then be rapidly fed back into adjusting forecasts, particularly until a routine LMIS is developed and implemented.

## 4.6 Logistics Management Information System

*The subcommittee recommends implementation of a LMIS for ARV tracking, which will begin as a vertical system, but, at a later date, will be designed to integrate other commodities.*

A well-functioning clinical records/reporting/monitoring system and LMIS for ART is critical for providing routine feedback from clinical and pharmacy records. This will allow toxicity, resistance, drop outs, and stock status to be detected and reported monthly, the forecast of needs adjusted, and the shipment quantities and product formulations changed as needed. Similarly, because of a highly mobile population, tracking patient treatment as the patient moves will be critical to maintaining as many patients as possible on first-line therapy.

The logistics subcommittee agreed unilaterally that without an effective and timely LMIS, the logistics functions of distributing ARVs to sites that need the drugs would be impossible. Although the committee was extremely reluctant to propose development of any vertical system, there was general agreement that given the high costs associated with ARVs, initially, the LMIS for managing these drugs may need to begin as a vertical system but should be designed so that it could be integrated with other health commodities at a future date. Although no concrete decisions were made on the LMIS design, the consultant was encouraged to provide more information on the feasibility and cost of three different approaches: manual, semi-automated, and fully automated (using technological innovations such as barcoding, smart cards, and hand-held devices).

## 4.7 Laboratory Requirements

*Procurement and logistics management of laboratory equipment and supplies required to support a national, expanded ART program is a critical, but often overlooked, area that needs to be addressed.*

Some basic key decisions have been made about the role of laboratory tests as they pertain to ART. The clinical care subcommittee has decided that viral load and CD4 counts are not critical requirements for initiating ART in the public sector; it has recommended a short list of basic minimum tests for ART. See table 1 for a list of essential and desirable tests recommended by the Clinical Care subcommittee.

**Table 1: Recommended Tests for Patients Accessing ART Through the Public Sector**

Level Available	Investigation		Test and Equipment Requirements
All levels	Absolute minimum tests	HIV antibody test	Rapid tests
		Hemoglobin or hematocrit	
	Basic recommended tests	Total WBC + differential	Hematology Analyser
District hospitals	Basic recommended tests	LFTs: alanine or aspartate aminotransferases	Clinical chemistry analyser
		Serum creatinine and /or blood urea	
		Serum glucose	
		Pregnancy test	
	Desirable test	Bilirubin	Urine sticks
Referral hospitals	Desirable test	Serum lipids	Clinical chemical analyzer
		CD 4 cell count	Flow cytometer/Facs count
Research centers	Optional tests	Viral load count	Viral load machine

It is clear that the logistics and procurement subcommittee must play a similar role for laboratory requirements as it plays for ARVs, namely that it will provide advice on quantification and procurement of equipment, reagents, and supplies and guidelines for logistics system implementation. However, the logistics subcommittee only co-opted a member with laboratory expertise in March 2003. Partly because of this, the issues related to procurement and logistics of laboratory supplies to support an expanded ART program have not been discussed or developed with the detail required for effective implementation.

The MOH, through MAP, is procuring equipment and reagents in readiness to support an expanded ART program. Selection of the equipment and reagents included input from UVRI and the laboratory at Mulago Hospital but not CPHLS.

## **5. Quantification of ARV Drugs for Public Sector Health Facilities Using World Bank MAP Funding**

### **5.1 Background**

The World Bank, through the MAP project, has allocated U.S.\$3 million to the Ministry of Health for the procurement of antiretroviral drugs for a one-year period. This is the first time that the MOH will procure ARV's for use in the public sector.

### **5.2 Objective**

To quantify national ARV requirements for treating patients in the public sector to be procured under the MAP project for 2003–2004.

### **5.3 Approach**

Because of the lack of data to guide such an exercise, the quantification relied heavily on assumptions of treatment and service utilization patterns developed with key informants. Key informants that provided critical information included Dr. Elly Katabira, Chairperson ARV clinical committee, who provided data on service statistics for ARV treatment in adults; and Dr Philippa Msoke, a committee member responsible for pediatric AIDS at Mulago Hospital. Dr. Peter Solberg of the Centers for Disease Control and Prevention also provided valuable information on dosages and prices, and he reviewed initial drafts of the quantification.

Information was collected on—

- Standard first- and second-line treatment algorithms recommended by the Clinical Care subcommittee of the ARV task force
- Pricing information from Joint Clinical Research Centers; Medical Access, the largest importer of ARVs in Uganda; CDC; and international prices for generic drugs (for which local prices are not available)
- Estimated percentages of patients that will receive first- and second-line drugs for both adults and children.

The quantification was conducted concurrently with the process of finalizing the clinical care guidelines. To enhance accuracy and build consensus, after each draft quantification was produced, it was shared with various members of the Clinical Care subcommittee for comment and further clarification. One advantage of the interaction between the two

processes was that the logistics consultants were able to provide the clinical care subcommittee members with a summary of the financial, and thus access, implications of certain drug choices and service utilization assumptions. When finalizing decisions on care, the subcommittee could make more informed choices about the program reach based on preliminary quantification results.

## 5.4 Assumptions

1. This quantification used a combination of morbidity and data on a target number of patients to be treated. A logistics-based forecast was not conducted because historical consumption data from the public sector was not available, and because the program cannot provide a full supply of ARVs for public sector requirements.
2. The quantities estimated assume that standard treatment guidelines for first- and second-line ART will be strictly adhered to in the public sector. See table 2.

**Table 2: Standard Treatment Regimes for ARV Drugs Recommended by the Clinical Care Subcommittee of the ARV Task Force, 1 March 2003**

Regimen	Drug Combination	Fixed-Dose Combinations	Pill Burden/ Patient/Day
<i>Adults First-Line</i>			
Option A	D4T(30 mg) + 3TC + NVP (i) and D4T(40 mg) + 3TC + NVP (ii)	D4T+3TC+NVP	(i) = 2 (ii) = 2
Option B	AZT + 3TC + NVP (i) or EFV (ii)	AZT + 3TC	(i) = 4 (ii) = 3
<i>Adults Second-Line</i>			
Option A	AZT + ddl + Kaletra	None	(i) = 10
Option B	D4T+ ddl + Kaletra	None	(i) = 10
<i>Children First-Line</i>			
Option A < 5 yrs	AZT syrup 3TC syrup NVP syrup	N/A	5–8 bottles per month per drug
Option B > 5yrs	D4T/3TC/NVP	½ tab of D4T+3TC+NVP	(i) = 1
<i>Children Second-Line</i>			
Option A	D4T+ ddl + Nelfinavir	None	8
Option B	AZT + ddl + Nelfinavir	None	8
<i>Others</i>			
TB patients (CD4 <50- 200)	D4T + 3TC + EFV (i) or AZT + 3TC + EFV (ii)	AZT + 3TC	(i) = 5 (ii) = 3
PEP	AZT + 3TC + Kaletra	AZT + 3TC	8
PMCT	Single dose NVP for mother and syrup for child	N/A	N/A



1. All adult and pediatric AIDS cases eligible for ART and targeted for drugs through the public sector will receive ARV's free or subsidized in the public sector. However, it was assumed that the majority of patients beginning treatment in the public sector would be receiving ARV drugs for the first time (ARV naïve) and, thus, eligible for the first-line treatment regime. In other words, it was assumed that patients currently accessing ART through the private sector—and undoubtedly receiving very different ARV regimes—would not switch to access free or subsidized public sector ARVs. If this situation were to occur on a wide scale, first-line treatment would most likely fail for these patients, and the funds spent on procuring ARVs (the majority first-line drugs) would be wasted.
2. Uganda's total population was assumed to be 24 million, based on recent census results. A national HIV prevalence rate of 6 percent was used based on the most recent surveillance report.<sup>8</sup> ACP/MOH estimates that there are 100,000 adult AIDS cases in Uganda, or approximately 7 percent of HIV+ individuals in the country.
3. Quantification has been done per 1,000 cases treated on an annual basis. The MOH anticipates more funding for ARVs through MAP and the GFATM for the next few years, so rather than quantifying for a limited number of patients for several years, the MOH requested a quantification for ARVs to cover as many patients as possible for one year. Using the factor of 1,000 cases provided in the quantification, program managers will be able to determine how many patients can be treated based on available funding levels, and adjust target population figures accordingly.

The following assumptions and percentages were provided primarily by Drs. Katabira and Msoke from the Clinical Care subcommittee:

1. Of 1,000 AIDS cases per year, 90 percent will be adults, and 10 percent will be children aged 1–12.
2. It is assumed that a very limited number of patients currently on ART, and paying for drugs through the private sector, will switch to access this supply of ARVs. The assumption is that the majority of patients who will access ARVs through the public sector are currently not receiving therapy. It is also assumed that very few of the patients that receive first-line drugs will need to switch to second-line drugs because of treatment failure during the first year.
3. Of 900 adults, 90 percent will receive first-line therapy (see sheet A, annex I). Of this 90 percent, the majority (95 percent) will receive option A or the fixed dose combination (FDC) for D4T+3TC+NVP. The quantification will refer to the most well known FDC for this regimen on the market Triomune, which comes in two dosages, 40 mg of D4T and 30 mg of D4T. It is recognized, however, that Triomune may not be purchased, but, rather, is an equivalent formulation. Because the majority of patients presenting for treatment initially are below 60kg, the assumption was that 40 percent of the 770 patients on option A will receive 30 mg Triomune for the whole year, while the remaining 60 percent will start on 40 mg. In reality, some individuals will switch to the higher dosage

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8 Uganda HIV/AIDS Surveillance Report. June 2002.

after six months, which is why a slightly higher percentage of 40 mg Triomune will be quantified.

4. Option B is reserved for the very small percentage that experience peripheral neuropathy from D4T, and for which single drug substitution will be required (AZT). Patients on option B will receive Combivir (AZT+3TC) and either nevirapine or efavirenz as loose drugs. Pill burden for EFV is a consideration, given that a new strength of 600 mg has just been released on the market, which would greatly enhance compliance by reducing the number of EFV pills from three to one a day. The small percentage of patients that experience peripheral neuropathy is likely to increase in year 2, but this is not factored into this quantification.
5. Of the 10 percent on second-line therapy, half will receive D4T plus ddI and Kaletra, while the remainder will receive AZT instead of D4T. The assumption was that of patients starting second-line therapy, as with first-line therapy, the majority will be below 60kg, and will be started on a lower dosage and switch to the higher dosage after six months. Thus, as in #8 above, quantification was done for 40 percent of patients receiving 250 mg of ddI and 30 mg of D4T, and 60 percent receiving 400 mg of ddI and 40 mg of D4T. Pill burden is a consideration here. Although 200 mg and 50 mg tablets of ddI are available, neither strength is registered in Uganda, only 100 mg and 25 mg are registered. Using registered strengths of ddI, the pill burden for adults >60kg just for ddI is four pills daily compared to potentially two daily. For adults <60kg, the ddI pill burden is four pills daily compared to potentially two.
6. Of 100 children, 90 percent will receive first-line therapy. Of those receiving first-line therapy, 70 percent will be under 5, divided between 18–24 month-olds (20 percent) and 2–5 year olds (80 percent). The remaining 30 percent will be between 5–12 years. Dosages for children are calculated by weight, with specific formulas of dosage per kilo. For the purposes of quantification, a standard dosage has been used for each subgroup of children, assuming children were at the top weight of that category.
7. Children under 2 will receive five bottles of each syrup a month, while 2–5 year olds will receive eight bottles of each syrup per month (see sheet C, annex I). It is assumed that all 5–12 year olds weigh less than 60kg, thus quantification was done for the 30 mg FDC (e.g, Triomune). Most (90 percent) of the 5–12 year olds will receive half the adult dose of 30 mg Triomune (1/2 tablet), while 10 percent will weigh enough to qualify for the full adult dosage of 30 mg Triomune.
8. The percentage of children receiving second-line therapy corresponds to those for first-line. The majority of first-line therapy consists of AZT, so 70 percent of children will receive D4T/ddI/NFV for the second-line regime and 30 percent will receive AZT/ddI/NFV. Again, it was assumed that all children under 12 weigh less than 60kg, so D4T of 30 mg and ddI of 250 mg dosages were used in the quantification. For children, half the adult dosages of each of D4T and ddI were quantified for. Similarly, half the adult dosage of NFV was used for quantification of needs.
9. Consideration for ARV drugs for TB/HIV patients was included in the numbers of patients who will receive option B of first-line and second-line drugs. It was assumed

that, as stated in the National ART Policy, the majority of patients will complete their TB therapy before starting ART, and thus receive option A of first-line drugs. Only those with CD4 counts of less than 200 will receive the TB specific regime.

10. Quantification for mothers receiving MTCT intervention of a single dose of nevirapine was not conducted, because this supply is already being provided through UNICEF and the Boehringer Ingelheim donation programme. Mothers who have received a single dose of NVP and have developed resistance are included in those patients accessing second-line treatment.
11. Quantification of drugs for PEP among health workers was also not conducted. It is the government policy that PEP will be provided; however, the clinical care committee decided that it was not prudent to order drugs for PEP until all sites are able to conduct rapid testing of both patient and health worker at the time of exposure to prevent misuse of ARVs for PEP purposes.
12. For this first round of quantification, primarily because so little data is available on toxicity/intolerance and failure rates, issues, such as patients switching from NVP and EFV due to rashes, were not included in the quantification. These should be addressed for quantification under GFATM.

Table 3 provides estimates for the specific categories of patients that will receive ARV drugs through the public sector.

**Table 3: Estimates for Number of Adults and Pediatric AIDS Cases That Will Receive ART Through the Public Sector**

Total population for 2002	24,000,000	A
Total number of people living with HIV/AIDS (A x 6 prevalence)	1,440,000	B
Total number of AIDS cases (B x 7 percent)	100,000	C
Total number of adult AIDS cases eligible for ART	<b>TBD</b>	D
Total number of adults AIDS cases eligible for ART that will access public sector health services	<b>TBD</b>	E
<b>Estimates of treatment based on 1000 AIDS cases a year</b>		<b>F</b>
Adult AIDS cases (F x 90 percent)	900	F1
Adult AIDS cases on first-line drugs (F1 x 90 percent)	810	F2
- Adult AIDS cases on option A of first-line drugs (F2 x 95 percent)	770	F2a
- Adult AIDS cases on option B of first-line drugs (F2 x 5 percent)	41	F2b
Adult AIDS cases on second-line drugs (F1 x 10 percent)	90	F3
Paediatric AIDS cases (F x 10 percent)	100	F4
Paediatric AIDS cases on first-line drugs (F4 x 90 percent)	90	F5
Paediatric AIDS cases <5 on first-line drugs (F5 x 70 percent)	63	F6
- Paediatric AIDS cases <2 on first-line drugs (F6 x 20 percent)	13	F6a
- Paediatric AIDS cases 2–5 on first-line drugs (F6 x 80 percent)	50	F6b
Paediatric AIDS cases >5 on first-line drugs (F5 x 30 percent)	27	F7
Paediatric AIDS cases on second-line drugs (F4 x 10 percent)	10	F8

## Uganda: Logistics and Procurement Decisions and Issues for Consideration for Initiating and Expanding Access to ARV Drugs

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1. To maximize the use of resources and reduce the amount of buffer stock required at ART treatment centres, it is assumed that the supply for adult cases receiving option B of first-line treatment and second-line drugs will be centrally maintained and sent out on an *as needed* basis. However, a 5 percent wastage rate was included in the quantification.
2. It was assumed there would be a zero stock balance of any of the ARVs upon delivery of the drugs to the warehouse.
3. The MOH anticipates that more MAP funding and GFATM will be available before December 2003 for more ARV drug purchases. However, until the financial flow and procurement systems are fully developed and clear, it was considered prudent to quantify for a buffer stock of four months (see sheet B, D, annex I). Although a six-month buffer stock is ideal, this was considered unaffordable in terms of the lost opportunity cost for treating a larger number of patients.
4. For EFV, a new strength of 600 mg branded tablets has just been put on the market by Merck & Co. This will reduce the patient pill burden from three tablets a day of EFV to just one tablet a day. Furthermore, the price of the 600 mg tablet is significantly lower than the generic cost for 200 mg tablets, by approximately \$100 per patient per year. Although the 600 mg strength of EFV is not registered in Uganda, NDA has received the Merck application to register the new strength, and they expect the process to be complete well before the product arrives in the country. Thus, quantification was done for the 600 mg strength tablet.
5. For ddI, a similar situation occurs where strengths of 200 mg and 50 mg tablets are not registered. However, although 200 mg is not registered, it has been used in the country and there is reason to believe its registration is pending. Thus, the quantification for adults factored in use of 200 mg instead of 100 mg, reducing the pill burden for the second-line regime from 12 to 10 pills daily. Because there is no record of the 50 mg product being used or pending registration, quantification was done using 25 mg strength, which is registered, to reduce potential delays in procurement. There was some discussion about the fact that if enteric coated (EC) ddI was not ordered, and the dosage was twice a day, then 100 mg pills would be required to provide sufficient buffer for absorption. However, the conclusion was that if 200 mg was dosed once a day, which does not compromise drug efficacy, this problem could be avoided.
6. Although local prices in Uganda shillings were preferred for costing, only JCRC provides prices in local currency and these are retail prices. Thus, the price list of Medical Access Uganda Ltd (August 2002) was used for the majority of branded products, while generic prices were obtained from MSF's December 2002 document entitled *Untangling the Web*. The annual price listed in the MSF document, was divided by 12 and used to provide a comparison generic cost to branded products available locally. If prices were not available from the MSF document, the branded price was listed instead. Generic prices were used even if the generic product is not registered in Uganda to give committee members an idea of potential cost savings. The JCRC prices (February 2003) were also used as a reference. See sheet E, annex I for detailed costs.

7. Cost comparisons were done for branded drug prices and generic drug prices. In some cases (EFV and Kaletra), branded drugs were significantly cheaper than generics, although, in most cases, generic costs were lower. A comparison was also done for total costs for the following two scenarios:
  - a. Scenario 1: for first-line drugs in adults, 70 percent are on option A (FDC for D4T+3TC+NVP) compared to 30 percent on option B of treatment (Combivir + NVP or EFV)
  - b. Scenario 2: for first-line drugs in adults, 95 percent are on option A (FDC for D4T+3TC+NVP) compared to 5 percent on option B of treatment (Combivir + NVP or EFV)

The results of adopting a less flexible prescribing scenario (95 percent limited to FDC for D4T+3TC+NVP) demonstrated an approximately \$50 cost savings per patient annually or the ability of the program to reach approximately 10 percent more patients (comparing lowest prices for treating 1000 patients annually).

8. No quantification was conducted for the lab supplies that will be required to complement initiation and maintenance of patients on ART.

## **5.5 Results**

See annex IV for the final quantities to order and the cost estimates. A cost comparison was done for branded and generic/lowest costs for total quantities required to treat 1,000 patients per year.

**Based on lowest cost estimates (either generic or branded) for each drug, it will cost approximately \$518,723 to treat 1,000 ARV cases per year or \$519 per patient per year.**

Although the lowest combination regimen on the market is estimated to cost \$350, calculating treatment costs for 1,000 patients captures costs associated with switching from first to alternate lines of therapy, costs for treating pediatric AIDS cases, and costs for a four-month supply of buffer stock.

It is important to note that this is just the cost of drugs required to provide ART and does not factor in the cost of other commodities, including lab supplies to support ART service provision or drugs for OI treatment or prophylaxis.



## **6. Policy Issues Defined by Logistics Subcommittee That Require Further Consideration**

### **6.1 Statutory Basis for Importation of Generic Drugs into Uganda**

*The logistics subcommittee discussed the importance of ensuring that Uganda's importation of generic drugs is consistent with TRIPS agreements but it takes advantage of DOHA concessions, and referred clarification of this issue and advocacy for final decision making to the policy subcommittee.*

Although NDA and MOH have adopted supportive positions for importation of generic ARVs into the country, there is a need to ensure that, as the program expands, Uganda is legally able to freely import generic ARV drugs, specifically the application of TRIPS under World Trade Organization (WTO) agreements. Uganda has established a special Parliamentary subcommittee to address TRIPS-related issues for drugs. Currently a “Proposed Industrial Property Bill 2002,” is being developed, and was originally intended to create a legal way for Uganda to import generic drugs based on WTO and TRIPS requirements. However, the bill does not take advantage of recent DOHA concessions, which consist of a ten-year extension of the transition period—from 2006 until 2016—for less developed countries to provide patent protection for pharmaceuticals. Thus, there is a need for MOH to conduct advocacy with the Ministry of Trade and Industry to ensure that the bill capitalizes on flexibilities within the agreement.

Uganda's National Drug Authority, which controls importation of all health commodities, has decided to take a neutral position on importation of generic ARVs, as long as quality of imported drugs is assured. Ministry of Health has included this stance on purchasing either generic or branded ARVs in its ART policy, which states that low-cost, high-quality drugs will be purchased, regardless of patent status, to support GOU's strategy on enhancing equitable access to ARVs for all Ugandans. NDA has also issued a position paper on local production, which is consistent with WHO recommendations, to provide guidelines to companies that plan to begin local manufacturing. Meanwhile, institutions and pharmacies that have been importing WHO prequalified generics continue to do so, as do new providers of ART, using a special NDA authorization process.

### **6.2 Free Versus Subsidized ARVs in the Public Sector**

*The policy regarding pricing of ARVs to patients in the public sector, which the Policy Subcommittee is currently finalizing, should ensure that the guidelines implemented will limit those who can pay from accessing free or highly subsidized drugs.*

The subcommittee identified two issues for consideration in this regard. The first issue relates to the need for a consistent policy for payment or non payment of these drugs. Currently, the draft policy includes the following decisions concerning free and subsidized drugs:

- ARVs for prevention (e.g., PMTCT and PEP services) will be provided free to patients.
- A sliding scale of fees for patients receiving ARVs for treatment, including free or highly subsidized drugs for those who cannot afford drugs and even full payment for those who can pay.

The policy statement highlights the fact that equity is a driving goal for the MOH, and it recommends that clear criteria be developed to determine how health workers and patients will be guided on the level of subsidy required, to ensure that equitable access is achieved.

Another issue to consider is the implication of providing free ARV drugs through the public sector. From a logistics perspective, a major issue to consider is whether a large population of patients currently on treatment will move from paying for drugs and services through the private sector to accessing these free or at highly subsidized costs through the public sector. If this happens on a large scale, the quantities estimated for procurement in chapter 5 will become significantly less useful. This is because the quantification was conducted on the assumption that a large percentage of patients starting ART in the public sector would be ARV naïve. If patients currently receiving different ART regimens through the private sector switched to free treatment through the public sector, there is a high likelihood of treatment failure for these patients. Regardless of the pricing policy selected, safeguards against such situations should be put in place to preempt wastage of resources.

### **6.3 Eligibility Criteria for Enrolling Patients**

*The Logistics Subcommittee recommends that the Clinical Care and Policy subcommittees develop clear eligibility criteria for patients receiving ARVs procured for the public sector.*

Currently, there is not enough money under MAP to procure ARVs for 100,000 PLWHA who are estimated to need the drugs. Combined MAP and GFATM funding levels will not even be sufficient to treat a *low* scenario of 10,000 patients. Although the policy document provides some guidance on policies around free and subsidized provision of ARVs, there are no clear selection/eligibility criteria for service providers to use when enrolling and treating patients.

Clear criteria for patient eligibility for ARVs are necessary for multiple purposes: to enhance equity and service provision and to ensure effective logistics management of ARVs. In developing these guidelines, one consideration that the subcommittees should keep in mind is accounting for changes in patient behaviour as ARV prices become more widely available at lower costs through the public sector. For example, one scenario is that a significant number of non-ARV naïve patients or patients receiving drugs through the private sector, switch to accessing drugs in public sector. This could potentially result in high failure rates for the ARVs quantified under MAP and used to treat the majority of public sector patients. Both subcommittees acknowledged that developing eligibility criteria that addresses this specific



issue will be challenging, given the lack of data available on patients currently receiving ART, but that it must be addressed in the criteria.

## **6.4 Revision of NDA Statute**

*The subcommittee recommends that the Policy Subcommittee support and provide input into the revision of the drug classification section of the NDA Statute to schedule ARVs as a subclass under Class A to enhance drug quality and monitoring.*

Currently there is no provision for ARVs within the system of classification of drugs. Class A drugs are usually highly controlled items, such as narcotics and psychotropics. Class B is the broadest category and includes the majority of prescription drugs, including anti-infectives, antibiotics etc. Class C are over-the-counter preparations. For the moment, until this issue is resolved, ARVs are classified as Class B items. Opinion in the logistics subcommittee was divided about whether ARVs should be classified as Class A or B. NDA is recommending Class A given the high level of abuse of many Class B drugs. The resistance to this suggestion is because committee members are worried that placing them in Class A will restrict their access and, thus, expansion of the ARV program. NDA has suggested reclassifying ARVs under Class A, but as a sub-class that is not as restricted as narcotics, although it still will allow sufficient control to ensure quality and reliability of the drugs. The recommendation is that the NDA statute pertaining to reclassifying ARVs be revised to ensure stricter control of these items.

The draft policy does not address this issue specifically, because the statute is currently undergoing review and revision, and it is anticipated that this will be addressed by the time the policy document is complete. There appears to be no resistance to the idea of classifying ARVs as a sub-class under Class A, as long as equity of access is not compromised. Immediate expansion plans include the regional hospitals and high-volume district hospitals, and, eventually, HC IV's, all of which have medical officers for prescribing ARVs (a basic requirement for Class A drugs).

## **6.5 Financing Logistics Management Costs: Procurement, Storage, Distribution, and LMIS**

*The Logistics subcommittee and financing committee must identify and develop mechanisms to ensure that there is a continuous flow of funds to procure ARVs, and for paying for logistics functions to ensure their uninterrupted supply through the in-country pipeline.*

Ensuring the financing flow for ongoing procurement of ARVs after patients have been enrolled for ART will be critical to ensuring a consistent flow of ARVs into the country, and, thus, down to the clients, especially because the program has decided to maintain only a four-month buffer stock for these items. Even a two-month delay between the funding cycles for MAP and GFATM could have serious ramifications for ARV availability and stockouts in Uganda, given the low level of buffer stock that will be provided.

Setting up guidelines for a similar mechanism at all implementing ART sites is also critical. Whether or not drugs will be provided free to patients, ART sites should establish separate accounts for procuring ARVs to minimize the risk that funds will be diverted to cover other expenses, thus leading to ARV stockouts.

Furthermore, despite available funding for procuring ARVs, and a decision that the drugs will be stored and managed through the existing systems such as NMS, no mention has been made of how the logistics management functions will be financed. The current practice is for NMS to include a 6–10 percent mark-up on the value of the drugs, which covers storage, handling, and distribution to district levels. If this model is followed, it is important that the value of the mark-up is carefully negotiated because of the high cost of ARVs. Although NMS has results from a study demonstrating that 10 percent does not cover their total costs, in the case of high-value items such as ARVs, this will obviously not be the case. It is also important to remember that the significant price reductions in ARVs that have occurred over a brief time, are mainly due to the increasing availability of generic drugs. Thus, any price negotiation based on value should consider possible devaluations in the price of ARVs over time. The price negotiation should consider extra measures that NMS will have to institute to ensure security of the supply.

Developing/maintaining a LMIS for ARVs is one extra logistics cost that has not been addressed for other essential medicines. Although the need for a tracking system for logistics information for all essential drugs has and continues to be expressed, lack of resources and political support for its development have prevented implementation of an LMIS for the majority of essential drugs. In contrast, because of the many enumerated risks related to expanding ART access in Uganda, including the high cost of drugs and risks of drug resistance, an LMIS is considered a critical intervention in ART implementation. Although it is too early to know the costs of developing such a system, the issue of allocating financial resources for its development and maintenance must be addressed. Without funding for this purpose, experience with the STI and other projects has shown that even after ARVs arrive in the country, they will probably not reach the ART centers on a regular and timely basis.

## **6.6 Standardizing Procurement Procedures and Coordinating Donated Products**

*Guidelines and a decision on aligning procurement procedures and ensuring coordinated procurement by several donors for ARVs will ensure that funding is used effectively, ARVs arrive regularly, and duplication of orders and wastage is minimized.*

Due to the potential risks of overstocking and understocking of ARVs associated with multiple sources of funding and procurement agents (each with different operational cycles), it is critical to ensure that there is a consistent approach in procurement procedures and that identical drugs are procured. Ideally, approaches for promoting procurement of quality drugs without limiting competition should be adopted, such as limited competitive bidding using prequalified suppliers and the use of uniform drug specifications by each procurement agent. NDA has suggested the following criteria for prequalifying suppliers that are eligible to respond to tenders for ARVs:

- manufacturers currently registered by NDA
- manufacturers of drugs prequalified by WHO or other internationally recognized bodies, such as MSF.

The policy document supports such an approach and recommends limited competitive tendering, based on WHO's prequalified list. The goal is both to ensure that high-quality drugs are procured and to minimize delays in the procurement process.

Although limiting the procurement procedures that can be used for ARVs is a necessary first step, a further complementary step required to reduce the risks of stockouts or overstocks is to ensure there is a mechanism for coordinating needs requirements, and procurement and shipments from multiple donors, given the fact that new donors and procurement agents are likely to emerge over time. One approach is to use the MOH's policy on target numbers of patients to treat over a specific period of time together with eligibility criteria to prepare a 3–5 year forecast for ARVs. This can then be used to develop a long-term procurement plan and coordinate procurements among various donors. One advantage of this approach will be that the MOH can be proactive in advocating for resource mobilization, because they will have a clear estimate of costs for treating more patients. Another advantage is that if more donors come on board, MOH has clearly defined estimates of needs and timing for when commodities are required, so the new donors can align their purchases with whatever is on hand or being purchased.

A further consideration over time relates to aligning procurement for ARVs with the procurement policy for all other essential drugs. At a Pharmacy Section/MOH and UHSSP-sponsored workshop on "Procurement of Medicines and Health Supplies" on March 19, 2003, the MOH and stakeholders agreed to begin the process of operationalising integration of procurement by contracting NMS as its primary procurement agency for drugs and health supplies.<sup>9</sup> A framework agreement (Memorandum of Understanding [MOU]) that will define responsibilities and fee structure to enable NMS procure, store, and distribute on behalf of donors, programs and projects will be developed. The MOU will ensure competitive pricing and performance against agreed benchmarks. If procurement of ARVs is aligned with MOH policy for other essential medicines, this will solve the problem of multiple agents with different procedures and cycles. Evidence has shown that without clear MOH direction and guidance on a preferred procurement agent, donor projects will make their individual and diverse procurement arrangements. There is little documentation on the performance of these arrangements. Overall, it appears that lead times are usually long, and irregular or interrupted supply is common due to inefficiencies in the tendering process, including the award of contracts for unregistered drugs.<sup>10</sup>

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9 Uganda Ministry of Health (MOH). March 2003. *Main recommendations of the health supplies procurement meeting held on the 19th march 2003*. Kampala, Uganda: Uganda Ministry of Health (MOH).

10 Uganda Ministry of Health (MOH). March 2003. *Health Supplies Procurement Meeting: In the spirit of SWAp*. Prepared for 19<sup>th</sup> March meeting by MOH Pharmacy Section and UHSSP. Kampala, Uganda: Uganda Ministry of Health (MOH).

## **6.7 Implementation of Uniform and Comprehensive Approaches to Data Collection and Management**

*The Logistics and Clinical Care subcommittees should identify and combine minimum essential data elements required for patient and drug monitoring, and develop a strategy for routine data collection, reporting, and analysis to assist with ongoing program management.*

Although each subcommittee has individually discussed the importance and need for data collection, the two have not yet worked together to determine data elements and implementation guidelines for the system. For many programs, health management information systems (for service utilization data) and LMIS (for logistics data) operate side by side as two separate, unlinked systems. In the case of ART, there are several benefits that could be achieved through linking or merging the two systems, including enhancing accountability of drugs consumed; identifying irrational prescribing; and dispensing patterns, and monitoring of toxicity and regime changes that will inform quantification of future supplies and feed into the resupply of drugs to each site. Ideally, all minimum essential data requirements, including those for financing, monitoring, and evaluation etc should also be identified and collected with service statistics and logistics data.

The clinical care committee has started working on a list of minimum data items that are required for ART monitoring of patients and, similarly, the logistics subcommittee has started the same process for logistics data required. It will be important to have a decision about whether to implement one integrated system or to have two separate systems.

Depending on the decision made as to how to collect, organize, and analyse patient and drug flow information—whether together or separately—a decision can then be made about implementing an LMIS.

## **6.8 Procurement and Supply Chain Management of Laboratory Equipment and Reagents**

*The role of each subcommittee—specifically the logistics subcommittee—in determining laboratory requirements and ensuring supplies of laboratory equipment and reagents should be clearly defined, including a decision on financing mechanisms for these commodities.*

The issue of laboratory supplies has not received the same focused attention as ARVs; thus, there are gaps in decisions in this area that require further clarification. Beyond the primary decision about which basic minimum tests are required for ART, detailed thinking has not progressed to the level of policy decisions concerning what organization will oversee laboratory requirements and supply chain management for equipment and reagents (CPHLS or UVRI). Similarly, key implementation guidelines—particularly regarding use and distribution of laboratory tests—need to be reviewed and enhanced. Mirroring the lack of clarity regarding institutional leadership for these items, there also appears to be a lack of priority within subcommittees as to what needs to be done for lab supplies and which subcommittees should provide leadership and guidance. It is particularly important to clarify

this because, currently, the logistics and clinical care subcommittees have limited laboratory expertise represented in their membership.

If laboratory supplies are to be integrated within the overall health care system, then, in theory, NMS should have the mandate for storage and distribution, under oversight from CPHLS. Furthermore, if a framework agreement for procurement is developed, then NMS will be the MOH's designated procurement agent, and will also be responsible for procuring laboratory supplies. Currently, there is no relationship between CPHLS and NMS in terms of procurement, handling, or storage and distribution. NMS does have the capacity to store and distribute these items, although, obviously, an MOU regarding the percentage markup for these items will have to be negotiated and developed, assuming funding is in place.

The two pressing questions that need to be addressed before further decisions on logistics system design and implementation can move ahead include—

- Which organization has the mandate for selection and oversight of supply chain management of laboratory equipment and supplies for ARVs and other HIV needs—CPHLS or UVRI?
- What is the source of funding for upgrading CPHLS to resume these responsibilities, including overseeing management of these supplies and training laboratory personnel?

## **6.9 Integrating Donated ARVs into the Supply Chain Management System for ARVs Purchased by the Public Sector**

*The Logistics and Policy Subcommittees should develop the policy and procedures for how donated ARVs will be integrated into the supply chain for ARVs purchased through the public sector.*

Although the majority of ARVs that will be used in the public sector will be procured by the public sector, there will be small quantities of ARVs donated for specific purposes or projects. In these cases, donated ARVs will be subject to the same policies as public sector procured ARVs, or will they follow the procedures that have been developed for all other donated drugs?

Issues to consider regarding donated ARVs include quality assurance, consistency with recommended standard treatment regimes for the public sector, financing for any logistics costs, and any potential costs of these donated drugs to patients. If donated drugs enter in large amounts for specific geographical regions or sites, this could potentially disrupt existing trends in consumption and distribution through NMS and ACP, which should be taken into account when developing procedures for logistics management of these items.



## 7. Recommendations for Implementation

### 7.1 Program Issues

*Recommendation 1: Improve supply chain management and procurement of associated HIV/AIDS commodities, including HIV testing, which is critical to the expansion of ART nationwide.*

#### Action Items

1. Ensure that the types of HIV test kits selected for procurement for VCT and PMTCT program expansion are user-friendly and practical for lower-level health facilities, thus enhancing ACP's ability to rapidly expand VCT and PMTCT service expansion.
2. Determine how HIV test kits—especially rapid tests that do not require refrigeration and are destined for VCT and PMTCT service expansion—will be stored and distributed.
3. Develop an agile supply chain management system for HIV test kits that will ensure that tests are distributed on a timely and regular basis to implementing sites, so they can be used prior to their expiry date.

*Recommendation 2: Revise national accreditation criteria for ART treatment centers to improve section on pharmacy, drug, and logistics management for public and private sector dispensing centers.*

#### Action Items

1. MOH and NDA and other relevant subcommittee members should revise the pharmacy, drug, and logistics management section of the accreditation requirements to expand criteria related to training, record keeping and reporting, inventory control, and storage.
2. Criteria for private sector dispensing sites for ARVs should include a requirement for general data on number of patients who received ARVs and quantities of drugs dispensed every six months.
3. Include professional organizations in the development of the criteria and develop a role for them in ongoing recertification or reaccreditation to ensure standards are maintained over time.

## **7.2 Product Selection and Registration**

*Recommendation 3: Any further product selection decisions should be shared with logistics subcommittee representatives to ensure that costs, storage, and distribution issues are considered.*

### **Action Items**

1. Ensure that the logistics subcommittee is regularly represented on the clinical care subcommittee to facilitate information sharing and to ensure that the clinical care subcommittee members are aware of logistics implications of product selection decisions.

*Recommendation 4: Implement procedures to minimize delays related to registration of new ARVs.*

### **Action Items**

1. To expedite importation process and minimize delays, encourage companies that win tender awards to submit importation documentation to NDA four weeks prior to the product arriving at the port.
2. Include a member of NDA on procurement committee for ARVs to minimize potential delays related to registration and importation.
3. Continue to strengthen capacity of NDA for inspection, quality control, and registration with an overall goal of reducing delays in registration and enhancing availability of data on drug quality. Specifically, capacity is required for training and evaluation in inspection of ARVs.

## **7.3 Quantification, Forecasting, and Procurement**

*Recommendation 5: Develop a 3-5 year forecast for ART and a corresponding, flexible procurement plan to allow for frequent shipments of small consignments of ARV drugs and coordinated donor inputs once new funding sources become available.*

### **Action Items**

1. Standardize procurement procedures, such as limited competitive tendering and specifications. to be used across different procurement agents.
2. To develop a forecast for 3-year ARV needs, the forecast should include a low, medium, and high scenario, the MOH and its partners should use decisions about targeted number of patients to treat and the number of implementing sites.
3. After the forecast and cost is known, develop a flexible procurement plan to ensure that even if funding is not available, resources can be mobilized to ensure that patients already started on treatment do not stop because of lack of funding.



4. Determine the mechanism for coordinating procurements and financing among various donors.
5. Determine a mechanism to ensure that changes in prescribing and dispensing practices that reflect drug substitution or switching regimens are rapidly incorporated into annual quantifications and forecasts.

*Recommendation 6: If uncertainties of funding are likely to cause bottlenecks in procurement, consider creating a fund for ARVs and other high-value public health commodities, such as TB drugs. This type of mechanism can be implemented at both the national and treatment levels.*

### Action Items

1. Logistics subcommittee members to work with financing committee to develop a mechanism to ensure a continuous flow of funds for ARV drug purchase for 5–10 years. Different approaches should be explored: a mini-basket for ARV drug purchase, a drug fund for high priority drug purchases e.g. ARVs, TB and anti-malarial drugs, etc.
2. Assign an institution, section, or body responsible for coordinating donor inputs into this mechanism.
3. Develop recommendations for implementation of the mechanism, including financing, administration, and management procedures, and ownership by the MOH or GOU.
4. Determine the mechanism for procurement coordination and decision making. Select an institution or body that is able to engage in dialogue and coordination between donors, procurement agencies, and programs within MOH.
5. Select the institution to work with the pharmacy section in MOH and donors to determine whether NMS can be the appointed agent for ARV drug procurement using all sources of funding.
6. If a single procurement agent is not feasible, select an institution to develop consensus on standard procurement procedures and specifications for ARV drugs, including consideration of limited competitive tendering using prequalified suppliers.
7. At lower levels, given a possible subsidy for patients to pay for drugs, determine how payment money will be collected and channeled towards repurchase of ARVs.
8. Determine financing mechanisms at implementing site levels to ensure that sites do not stock out of drugs due to lack of funds or interruptions in financing sources.

*Recommendation 7: Determine and clarify procedures for procurement and logistics management of laboratory supplies to support expanded ART service provision.*

### **Action Items**

1. MOH to confirm decision that CPHLS will resume mandate for operational management and supervision of laboratory equipment and supplies for HIV items, including those to support an expanding ART programme.
2. Define roles and responsibilities for CPHLS and UVRI about these items.
3. Conduct advocacy among development partners to solicit resources (financial and technical) to upgrade capacity of CPHLS to support new responsibilities.
4. As part of guideline development for CPHLS in the area of HIV lab supplies, ensure procedures for logistics management are defined and documented.

## **7.4 Logistics Management Information System**

*Recommendation 8: Ensure that a functioning LMIS and inventory control system is in place prior to the arrival of ARVs.*

### **Action Items**

1. Determine the list of essential logistics and other data elements that must be collected to facilitate logistics system functioning. Ensure this is coordinated with the data requirement list currently under development by members of the Clinical Care subcommittee.
2. Decide on the scope of the information system or systems that will be implemented, either jointly for collecting all ARV-related data or individually for different components (i.e., clinical, logistics, financing, etc.).
3. Explore cost, feasibility, and buy-in for three different models: manual, semi-automated, or fully automated. Include consideration of locally available technological innovations (e.g., smart cards, palm pilots etc.).
4. After design of system has been determined, define procedures for information gathering, reporting, and analysis, and document them in a procedures manual for each level and site. Procedures should also be developed or refined for inventory management at all levels, with the goal of ensuring secure storage and distribution throughout the supply chain.
5. Begin system implementation by pilot testing it in sites that already provide ART. As part of system rollout, develop job aids to alleviate the daily workload of health workers in using and maintaining system.
6. Ensure that final system is owned by and closely linked with all other MOH systems (HMIS, NMS, etc.).

## 7.5 Inventory Management, Storage, and Distribution

*Recommendation 9: Develop mechanism for ARV drugs to be securely stored and distributed through NMS.*

### Action Items

1. Develop a service agreement with NMS to outline performance measures for secure storage and distribution of ARVs through NMS. Agreement should include consideration of storage criteria to ensure security and quality, frequency, and mode of transportation; mechanisms for responding to requests from implementing sites; and mechanisms for obtaining allocation lists for distribution from MOH counterparts, including all other components of the agreement.
2. Conduct a rapid analysis of what mark-up should be agreed on for NMS to store and distribute ARVs. Currently, most programs pay 10 percent, while MAP pays 6.5 percent. Given the high value of ARVs, a much lower percentage will need to be negotiated, although not so low as to prevent NMS from effectively providing the service.
3. Another issue to consider in developing the service agreement is how NMS will be paid, both for storage and distribution, and, if implementing sites will be required to pay NMS for the drug supply.



## **Annex 1**

# **Scope of Work**



**Annex 1**  
**Scope of Work**  
**ARV Logistics Technical Assistance**

*February 24–March 4, 2003*

*March 17–March 28, 2003*

**Antiretroviral Task Force—Technical Assistance  
Consultancy**

**Background**

In November 2002, the AIDS Control Program within the Uganda Ministry of Health (MOH) established a multi-sectoral and cross-discipline Antiretroviral Task Force to guide the Government of Uganda and the MOH on introducing and expanding antiretroviral therapy (ART) in both the public and private sectors. The Task Force reports to the Ministry of Health and is chaired by Dr. Peter Mugenyi of JCRC. The Task Force consists of five subcommittees; Policy, Clinical Care, Advocacy, Logistics, Finance, and Coordination. Steve Wilbur of DELIVER is chairman of the logistics subcommittee, and DELIVER staff participate in the policy and finance committee meetings.

The various subcommittees have been quite active and have met regularly during the past three months. Key decisions are being made. Preliminary recommendations on key policy issues are emerging from each new meeting.

The logistics group has collected most of the available material on the ARV services currently in the country. It has also actively challenged the other subcommittee to define and finalize key policy issues that must be decided before final decisions and final quantification can be done.

One immediate goal of this process to define ARV national policy is to assist the MOH/GOU in preparing a major project proposal to be submitted to the GFATM in round three, anticipated in April 2003. For this submission, it will be necessary to include both proposed policies and procedures for ART treatment, as well as quantification for commodities to be requested under the GFATM project.

In addition to an anticipated request for ARV commodities from the GFATM, there is an immediate opportunity for the MOH to acquire several million dollars in ARV drugs, through the MAP Project. The MOH and DELIVER are presently doing quantification for these drugs, with commodities possibly arriving in Uganda by July/August 2003.

Yasmin Chandani has worked with HIV/AIDS and ARV logistics for the DELIVER project for the past few years. She has recently participated as the logistics specialist on the Kenya ARV Assessment working with Dr. Peter Mugenyi of JCRC to produce a comprehensive policy issues document for NASCOP/Kenya. She has also worked closely with the ACP

## **Uganda: Logistics and Procurement Decisions and Issues for Consideration for Initiating and Expanding Access to ARV Drugs**

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section in Uganda on HIV test kits, sexually transmitted infection (STI), and opportunistic infection (OI) quantification, so she is very familiar with the MOH program in Uganda.

### **General Scope of Work**

1. Assist the ARV Logistics and procurement subcommittee to document relevant logistics information and key policy decisions available to date.
2. Identify outstanding critical issues that still must be addressed.
3. Help plan the additional work that the logistics subcommittee must complete.

This assistance is needed because the subcommittee's individual members do not have sufficient unplanned time to accomplish these tasks, and the tasks need to be completed within the upcoming month.

### **Specific Scope of Work**

1. Meet with the logistics subcommittee members and relevant participants to gather and verify key logistics information and decisions already made.
2. Help define other logistics information that is needed to design an ARV logistics procurement and distribution system.
3. Help the subcommittee define whether a specific logistics assessment is needed or whether a larger review, including logistics issues, would be more appropriate.
4. Prepare a written document addressing the issues above and debrief the subcommittee.
5. Collect information on HIV test Kit procurement and planning and PMTCP nevirapine planning as it might effect ARV distribution.
6. Help finalize MOH quantification and purchasing requirements to be made to the MAP/WB Project for ARV commodities.
7. Help plan the TOR for a subsequent logistics assessment or for a logistics component in a larger countrywide ARV readiness assessment, if required.
8. Participate in a planning session with AIM, the Services Project, CMS, and USAID on logistics issues and coordination at the district level, with particular reference to ARV introduction on March 4.
9. Prepare a draft report and debrief the subcommittee and USAID.



## **Annex 2**

# **Schedule of Activities**



## **Schedule of Activities**

### **Monday, 24 February**

Owen Smith, PHR+ Abt Associates, Consultant to Finance Subcommittee

### **Tuesday, 25 February**

ART General Task Force Meeting

### **Wednesday, 26 February**

Dr. Catherine, PHR+ Abt Associates, Consultant to Policy Subcommittee

Marty Makinen, PHR+ Abt Associates, Consultant to Policy Subcommittee

Dr. Elizabeth Madraa, Programme Manager, ACP/MOH

Dr. Zainab Akol, VCT Manager, ACP/MOH

Dr. Elizabeth Namagala, ARV Manager, ACP/MOH

### **Thursday, 27 February**

Dr. Elly Katabira, Consultant Physician/Mulago Hospital and Chair of Clinical Care Subcommittee

Dr. Phillipa Msoke, Chief Pediatrician, Mulago Hospital/Johns Hopkins University Clinic

Martin Shiere, TASO Private Sector Consultant

Logistics Subcommittee meeting

### **Friday, 28 February**

Suzanne McQueen, USAID

Dr. Elizabeth Namagala, ARV Manager, ACP/MOH

Sailesh Savani, CEO, The Lynx Group (by phone)

### **Saturday, 1 March**

Clinical Care Subcommittee Meeting

Marty Mackinen, PHR+ Abt Associates, Policy Subcommittee consultant

### **Monday, 3 March**

Kate Kikule, NDA

Francis Otim, NDA

### **Tuesday, 4 March**

Dr. Peter Mugenyi, Head JCRC, Chair/ARV Task Force (by phone)

### **5 March–16 March (not included in consultancy)**

### **Monday, 17 March**

Dr. Elizabeth Namagala, Secretary, ARV Task Force all subcommittees

**Tuesday, 18 March**

Dr. Elly Katabira, Consultant Physician/Mulago Hospital and Chair of Clinical Care Subcommittee  
Dr. Phillipa Msoke, Head Paediatrics Dept., Makerere University and Head Paediatrician Mulago Hospital/Johns Hopkins University Clinic (by phone)  
Constance D, Head of Labs, Mulago Hospital, Johns Hopkins University Clinic  
John Omiat, Procurement Officer, UAC HIV/AIDS Project, MAP  
Dr. Alex Opio

**Wednesday, 19 March**

MOH meeting on “Health Supplies Procurement Meeting: In the spirit of SWAp.”

**Thursday, 20 March**

Mrs. S. Okui, Acting Chief Laboratory Technologist, Central Public Health Laboratories

**Friday, 21 March**

Dr. Elizabeth Namagala, ARV Manager, ACP/MOH  
Dr. Zainab Akol, VCT Manager, ACP/MOH

**Monday, 24 March**

Joseph Mwoga, Regional Pharmacist, Pharmacy Section, MOH  
Dr. Elizabeth Namagala, ARV Manager, ACP/MOH (by phone)  
Mr. Joseph Serutoke, Logistics Advisor, WHO (by phone)  
Raveena Chowdhury, Technical & Logistics Advisor, Reproductive Health, MOH

**Tuesday, 25 March**

Tom Brown, Crown Agents  
Logistics Subcommittee meeting

**Wednesday, 26 March**

Field visit to Masaka, “Uganda Cares” HIV/AIDS clinic (provides ARVs, VCT, and other HIV support services)  
Annik Hamel, Global Coordinator for Access to Essential Medicines, MSF  
Catherine Hamel, Country Rep, MSF

**Thursday, 27 March**

Finance Subcommittee meeting  
Dr. Elizabeth Namagala, ARV Manager, ACP/MOH (by phone)  
Dr. Zainab Akol, VCT Manager, ACP/MOH  
Suzanne McQueen, USAID  
Vastha Kibirige, Condom Coordinator, ACP/MOH

### **Annex 3**

## **List of Accredited Centers and Pharmacies Authorized to Distribute Antiretrovirals**



## **List of Accredited Centers and Pharmacies Authorized to Distribute Antirivirals**

### **List of Authorized Pharmacies as of February 2003**

#### **Importers**

1. Medical access
2. National medical stores
3. Joint medical stores
4. Joint clinical research center
5. Star pharmaceuticals
6. Shurik
7. Mednet (U) Ltd.
8. Surgipharm (U) Ltd.

#### **Retailers**

1. René pharmacy
2. City pharmacy

#### **Accredited Center**

1. Public health institutions
2. Mulago national referral hospital
3. Mbarara university teaching and referral hospital
4. Mbale regional hospital
5. Gulu regional hospital
6. Arua regional hospital
7. Kabale regional hospital
8. Masaka regional hospital
9. Soroti regional hospital
10. Makerere university hospital
11. Kalongo hospital

#### **Private and NGO Health Institutions**

1. Joint clinical research center
2. Midmay international center
3. Nsambya hospital
4. Rubaga hospital
5. Mengo hospital
6. Lacor hospital
7. St. Joseph Kitgum
8. International medical center
9. Case medical center
10. Victoria medical center
11. Kololo hospital
12. Kadic medical center

**Uganda: Logistics and Procurement Decisions and Issues for Consideration for Initiating and Expanding Access to ARV Drugs**

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- 13. Africa air rescue (AAR)
- 14. Bank of Uganda staff clinic
- 15. The surgery



## **Annex 4**

# **Results of ARV Quantification**



# **Report from Site Visit to Masaka Regional Hospital ARV Treatment Center**

**March 26, 2003**

## **Masaka Hospital ART center**

Masaka hospital is a regional hospital that is accredited to provide ART services. It has a center, which resulted from a partnership of various NGOs, MOH, and District local council. The center treats 100 patients, both adults and children. It has two medical doctors; one nurse who handles the store, and dispenses and keeps the records; and one laboratory staff employed by AIC. The center has one PC for data management. The clinic is run twice a week. Nationally recommended laboratory tests for patients on ART are performed three times a year.

Each partner plays a different role: AIC carries out VCT and recommends the individuals to TASO, Nsanbya hospital, and other local NGOs. The NGOs then identify and recruit patients. Patients are, thereafter, screened for eligibility based on clinical criteria, and after treatment commences.

Criteria for eligibility:

- Cd4 count of less than 150
- Based in or around Masaka (district)
- Strict adherence to schedule

The center stores the ARVs on site under tight lock and key with only one person in charge of keys (the nurse) and the same person dispenses the drugs. To avoid leakage, the nurse keeps records of the patients who receive the drugs, which is crosschecked on the same day, by the prescribing medical officer. Thereafter, a physical inventory is conducted.

To follow up on the habits and adherence to taking the medications, patients are required to return the empty bottles of the drugs. This is deemed useful in two ways:

1. To see whether the patient actually swallowed all the medicine and if some is remaining. ascertain what actually happened and avoid reoccurrence.
2. To ensure that the medicine is not being used elsewhere.

Overall, there were no stockouts of drugs reported, and adherence was reported at over 90 percent.